IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

SHERRY FOX, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-0878

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Defendants' Motion for Summary Judgment)

Pending before the court is the defendants' Motion for Summary Judgment [ECF No. 92]. As set forth below, the defendants' Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to the court by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately XXXXX of which are in the Ethicon, Inc. and Johnson & Johnson, Inc. ("Ethicon") MDL, MDL 2327. In an effort to efficiently and effectively manage this massive MDL, the court decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled

on all summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, the court ordered the plaintiffs and defendant to submit a joint list of 200 of the oldest cases in the Ethicon MDL that name only Ethicon, Inc., Ethicon, LLC, and/or Johnson & Johnson. These cases became part of a "wave" of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order No. 193, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002327, Aug. 19, 2015, *available at http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html*. This selection process was completed three times, creating three waves of 200 cases, Wave 1, Wave 2, and Wave 3. The plaintiffs' case was selected as a Wave 1 case.

On December 5, 2002, Ms. Fox was surgically implanted with the defendants' Gynecare TVT, a product manufactured by Ethicon to treat POP and SUI. Am. Short Form Compl. ¶¶ 9–10 [ECF No. 24]. Ms. Fox's surgery occurred at Fort Duncan Medical Center in Eagle Pass, Texas. *Id.* ¶ 11. Ms. Fox claims that as a result of implantation of the Gynecare TVT, she has experienced multiple complications. She brings the following claims against Ethicon: negligence, strict liability manufacturing defect, strict liability failure to warn, strict liability defective product, strict liability design defect, common law fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express and implied warranties, violation of consumer protection laws, gross

negligence, unjust enrichment, loss of consortium, punitive damages, and discovery rule and tolling. *Id.* ¶ 13.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise,

conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, the court generally refers to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Fox did in this case, the court consults the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, the court will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Fox received the Gynecare TVT implantation surgery in Texas. Thus, the choice-of-law principles of Texas guide the court's choice-of-law analysis.

The parties agree, as does the court, that these principles compel application of Texas law to the plaintiffs' claims. In tort actions, Texas adheres to the Restatement (Second) of Conflict of Laws (Am. Law Inst. 1971). *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under section 145 of the Restatement (Second) of Conflict of Laws, the court must apply the law of the state with the most "significant relationship to the occurrence and the parties." Here, the plaintiffs reside in Texas, and the product was implanted in Texas. Thus, the court applies Texas's substantive law to this case.

III. Analysis

The defendants argue they are entitled to summary judgment because the plaintiffs' legal theories are without evidentiary or legal support. In their Response

[ECF No. 102], the plaintiffs withdraw several of the Counts listed in their Amended Short Form Complaint: Count IV, strict liability defective product; Count VI, common law fraud; Count VII, fraudulent concealment; Count VIII, constructive fraud; Count IX, negligent misrepresentation; Count X, negligent infliction of emotional distress; Count XI, breach of express warranty; Count XII, breach of implied warranty; Count XIII, violation of consumer protection laws; and Count XV, unjust enrichment. Accordingly, the defendants' Motion with regard to these claims is **GRANTED**. Below, the court applies the summary judgment standard to each remaining claim.

A. Strict Liability

Texas has adopted the doctrine of strict liability for defective products set forth in section 402A of the Restatement (Second) of Torts. *See McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 789 (Tex. 1967). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (Am. Law Inst. 1965). "The concept of defect is central to a products liability action brought on a strict tort liability theory, whether the defect be in conscious design, or in the manufacture of the product, or in the marketing of the product." *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979).

1. Failure to Warn

Texas, like many jurisdictions, has adopted the learned intermediary doctrine. Under this doctrine, a plaintiff must establish two elements: "(1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (applying Texas law).

Under Texas law, causation—the second element—must be proven by showing "a proper warning would have changed the decision of the treating physician." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)). In other words, the plaintiff must show "that but for the inadequate warning, the treating physician would have not used or prescribed the product." *Id.* (quoting *Dyer*, 115 F. Supp. 2d at 741). If a physician, as the learned intermediary, does not testify that he or she would not have used or prescribed the product, the causal chain is broken, the plaintiff cannot show causation, and the failure to warn claim fails. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012) ("[W]hen the prescribing physician is aware of the product's risks

and decides to use it anyway, any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries.").

The defendants argue that Ms. Fox's implanting physician, Dr. Warner, testified that, even if he had received an adequate warning regarding any chronic inflammatory reaction to polypropylene mesh and dyspareunia or erosion, such warnings would not have changed his mind regarding his desired course of treatment for Ms. Fox. Warner Dep. 39:12–25, Oct. 26, 2015 [ECF No. 92-1] ("I have to answer truthfully that it probably wouldn't have changed my idea of what may have been best for the patient at that point in time and what was available."). Thus, the court **FINDS** that the plaintiffs are unable to prove that Ms. Fox's treating physician would have refrained from prescribing the TVT had he received adequate warnings.

The plaintiffs' argument that the court should consider what Ms. Fox would have done had she been adequately warned (i.e., deciding to refrain from having the TVT surgery) is unpersuasive. Under Texas law, the learned intermediary doctrine focuses on the adequacy of the warnings to, and the behavior of, the physician, who may make individualized medical judgments "bottomed on a knowledge of both patient and palliative." *Centocor, Inc.*, 372 S.W.3d at 159 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). What the plaintiffs would or would not have done had they received certain warnings is irrelevant to the learned intermediary doctrine. *See Lewis v. Johnson & Johnson*, 601 F. App'x 205, 208 (4th Cir. 2015) (applying Texas law) ("When a plaintiff offers no evidence that a different

warning would have changed her physician's decision to prescribe a device, the inadequate warning cannot have caused the plaintiff's injury.").

The plaintiffs' strict liability failure to warn claims must fail because the plaintiffs are unable to prove that the alleged failure to warn was the producing cause of Ms. Fox's injury. Accordingly, the defendants' Motion on this point is **GRANTED**.

2. Design Defect

In Texas, a plaintiff bringing a design defect claim under strict liability must prove by a preponderance of the evidence that (1) the product was unreasonably dangerous due to a defect, (2) "there was a safer alternative design," and (3) "the defect was a producing cause" of the damages. Tex. Civ. Prac. & Rem. Code Ann. § 82.005; *see also Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009).

The defendants' Motion seeks summary judgment on the plaintiffs' design defect claims on the sole basis that the plaintiffs have failed to show the existence of a safer alternative design. To determine there was a safer alternative design, a plaintiff must prove that "an alternative design (i) would in reasonable probability have prevented or significantly reduced the risk of the claimant's injury or damage (ii) without substantially impairing the product's utility, and (iii) was economically and technologically feasible when the product was manufactured or sold." *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999). Proving the existence of a safer alternative design is a prerequisite to liability under Texas law. *Id.*

The plaintiffs have proffered extensive evidence of three alternative designs:

(1) polyvinylidene fluoride ("PVDF"), (2) laser cut edges, and (3) larger pore and lighter weight mesh. The plaintiffs have produced evidence that these purported safer alternative designs would have reduced Ms. Fox's injuries, would not have affected the product's utility, and would have been economically and technologically feasible. Accordingly, the court **FINDS** that there remains a genuine dispute of material fact regarding the existence of a safer alternative design under Texas law. The defendants' Motion on the plaintiffs' strict liability design defect claim is **DENIED**.

3. Manufacturing Defect

"A manufacturing defect exists when a product deviates, in its construction and quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006) (quoting *Ford Motor Co. v. Ridgway*, 135 S,W.3d 598, 600 (Tex. 2004)). "A plaintiff must prove that the product was defective *when it left the hands of the manufacturer* and that the defect was a producing cause of the plaintiff's injuries." *Id.*

The plaintiffs have failed to proffer sufficient evidence to survive summary judgment on their manufacturing defect claim. The sum total of the plaintiffs' evidence regarding their manufacturing defect claim originates not from their own experts, but from the defendants' expert, Dr. Irwin. According to the plaintiffs, Dr. Irwin testified that she would look to the "physical properties" of the TVT as a cause of extrusion after conducting a process of elimination. Resp. 18. Also, the plaintiffs

point to Dr. Irwin's statement that she would not *expect* an edge exposure from a "normal TVT." *Id.* Thus, according to the plaintiffs, Dr. Irwin's testimony "springboards the inference that a person should only expect to see an edge if the TVT edge was *not* normal. This is sufficient circumstantial evidence under Texas law of a manufacturing defect." *Id.* The court disagrees.

First, the plaintiffs have provided no evidence that a manufacturing defect existed at the time the device left the hands of the manufacturer. Second, the plaintiffs' reliance on Dr. Irwin's testimony is misplaced. Dr. Irwin is a gynecologist and is board-certified in several sub-fields of gynecology. Pls.' Mem. Supp, Mot. Exclude Test. re: Dr. Irwin 1–2 [ECF no. 97]. Dr. Irwin has no specialized skill, knowledge, education, experience, or training regarding the defendants' manufacturing process for TVT that would make her qualified to opine on such matters.[1] Finally, under Texas law, an expert may not prove a manufacturing defect merely by the process of elimination. *See Cooper Tire & Rubber Co.*, 204 S.W.3d at 807–08 (deciding that expert testimony attempting to eliminate other causes was legally insufficient to establish a manufacturing defect). Thus, drawing all inferences in the light most favorable to the plaintiffs, the court **FINDS** that the plaintiffs have failed to proffer more than a scintilla of evidence demonstrating that the TVT device implanted in Ms. Fox "deviated, in construction or quality, from the specifications or

[1] "Physical properties" of the TVT can also refer to the design of the device. Dr. Irwin's intended meaning of these words is unclear, but the court must draw all reasonable inferences in favor of the plaintiffs for the purpose of ruling on the defendants' Motion. Accordingly, the court will assume that "physical properties" refers to alleged manufacturing defects.

planned output in a manner that renders it unreasonably dangerous." *Id.* at 800. The defendants' Motion regarding the plaintiffs' manufacturing defect claims is **GRANTED**.

B. Negligence and Gross Negligence

"While strict liability focuses on the condition of the product, '[n]egligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production.'" *Am. Tobacco Co.*, 951 S.W.2d at 437 (quoting *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)). "Negligent design and manufacturing claims are predicated on the existence of a safer alternative design for the product." *Id.* The defendants argue only that summary judgment is proper on these claims because the claims are duplicative of the strict liability claims and because the plaintiffs have allegedly failed to offer evidence of a safer alternative design. As discussed above, the plaintiffs have proffered sufficient evidence regarding the alleged existence of a safer alternative design, and the plaintiffs' negligence claims are not contingent on the outcome of their strict liability claims; they are independent claims. The defendants' Motion regarding the plaintiffs' negligence claims is **DENIED**.

Under Texas law, gross negligence includes two elements:

> (1) viewed objectively from the actor's standpoint, the act or omission must involve an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and

> (2) the actor must have actual, subjective awareness of the risk involved, but nevertheless proceed in conscious indifference to the rights, safety, or welfare of others.

Mobil Oil Corp. v. Ellender, 968 S.W.2d 917, 921 (Tex. 1998). "Evidence of simple negligence is not enough to prove either the objective or subjective elements of gross negligence." *Id.* The plaintiffs offer evidence that Dr. Klinge published his findings regarding chronic inflammation and Prolene in 1999, and yet the TVT IFU described the foreign body reaction to Prolene as "transitory." The plaintiffs have also offered extensive evidence regarding the complications associated with chronic inflammatory responses to the TVT. Whether such complications pose the type of "extreme degree of risk" that would implicate liability for gross negligence is best suited for the trier of fact. The defendants' Motion regarding the plaintiffs' gross negligence claims is **DENIED**.

C. Loss of Consortium, Punitive Damages, and Discovery Rule & Tolling

The defendants assert that their Motion challenges all of the plaintiffs' claims, which include loss of consortium, punitive damages, and discovery rule and tolling. Mot. Summ. J. 1. The defendants, however, do not present any arguments regarding these claims. The court will not make arguments for the defendants. Accordingly, the defendants' Motion regarding the plaintiffs' claims for loss of consortium, punitive damages, and discovery rule and tolling is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that the defendants' Motion for Summary Judgment [ECF No. 92] is **GRANTED in part** and **DENIED in part**. As the plaintiffs have conceded these claims, the defendants' Motion is **GRANTED** with regard to the plaintiffs' claims for strict liability defective product, common law fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express warranty, breach of implied warranty, violation of consumer protection laws, and unjust enrichment. The defendants' Motion regarding the plaintiffs' strict liability manufacturing defect claims and strict liability failure to warn claims is **GRANTED**. The defendants' Motion regarding the plaintiffs' strict liability design defect, negligence, gross negligence, loss of consortium, punitive damages, and discovery rule and tolling is **DENIED**.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: July 8, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE